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Drug Companies' Liability for the Opioid Epidemic

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The opioid epidemic has claimed more than 300,000 lives in the United States since 2000[1] and could claim another half million over the next decade. Although heroin and illicitly manufactured fentanyl account for an increasing proportion of opioid-involved overdoses, the majority of persons with opioid addiction started with prescribed painkillers.[2] The search for solutions has spread in many directions, and one tentacle is probing the legal accountability of companies who supply opioids to the prescription market. Even as the federal government, among others, pursues civil and criminal actions against physicians and pharmacies to address inappropriate prescribing and dispensing of opioids, a variety of lawsuits have been filed and continue to be filed against opioid manufacturers and distributors.[2]

These lawsuits commenced in the early 2000s but have increased in frequency and profile in recent years (see table). The earliest suits against opioid manufacturers — typically Purdue Pharma, the maker of OxyContin (oxycodone) — were personal injury claims brought on behalf of persons with addiction who overdosed.

Opioid products, they alleged, were defectively designed because companies failed to include safety mechanisms, such as an antagonist agent or tamper-resistant formulation.[3] Manufacturers also purportedly failed to adequately warn about addiction risks on drug packaging and in promotional activities. Some claims alleged that opioid manufacturers deliberately withheld information about their products' dangers, misrepresenting them as safer than alternatives.[3]

These suits faced formidable barriers that persist today. As with other prescription drugs, it is challenging to persuade a jury that an opioid is defectively designed if the Food and Drug Administration approved it. Furthermore, in most states, a drug manufacturer's duty to warn about risks is limited to issuing an adequate warning to prescribers, who are responsible for communicating with patients. Finally, juries may resist laying legal responsibility at manufacturers' feet when the prescriber's decisions and the patient's behavior contributed to the harm. Some individuals do not take opioids as prescribed or purchase them illegally.

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Companies may argue that such conduct precludes holding manufacturers liable, or at least should reduce individuals' damages awards.[3]

One procedural strategy adopted in opioid litigation that can help overcome defenses based on users' conduct is the class action, brought by a large group of similarly situated individuals. In such suits, the causal relationship between the companies' business practices and the harm is assessed at the group level, with the focus on statistical associations between product use and injury. The use of class actions was instrumental in overcoming tobacco companies' defenses based on smokers' conduct. But early attempts to bring class actions against opioid manufacturers encountered procedural barriers. Because of different factual circumstances surrounding individuals' opioid use and clinical conditions, judges often deemed proposed class members to lack sufficiently common claims.[3]

The tide may turn for such lawsuits, however. As the population harmed by opioids grows and more information about them is documented, it becomes easier to identify subgroups with similar factual circumstances and legal claims — for example, newborns with neonatal abstinence syndrome. A class action brought against Purdue Pharma in Canadian court by persons who were prescribed and ingested OxyContin and OxyNEO (controlled-release oxycodone), which alleged claims similar to those in many U.S. cases, is on the verge of being settled for $20 million, if all involved provinces agree (see table).

Perhaps the most promising development in opioid litigation has been the advent of suits brought by the federal government and dozens of states, counties, and cities. Because the government itself is claiming injury and seeking restitution so that it can repair social systems debilitated by opioid addiction, these suits avoid defenses blaming opioid consumers or prescribers. They also garner substantial publicity.

Government strategies include traditional types of enforcement actions based on the federal Food, Drug, and Cosmetics Act, which prohibits introducing "misbranded" drugs into interstate commerce. However, governments have recently embraced several more creative strategies, borrowing from playbooks used for suing tobacco and firearm companies.

The first strategy focuses on the public scourge created by the opioid epidemic. Governments allege that opioid companies unreasonably interfered with the public's health by oversaturating the market with drugs and failing to implement controls against misuse and diversion, creating a "public nuisance." State attorneys general made similar arguments about firearm manufacturers, which allegedly knew that the high volume of guns they were supplying could find buyers only on the black market.

The second strategy paints opioid companies' business practices as deceptive. In these fraud claims, sometimes brought in connection with Medicaid claims or consumer protection laws, governments charge that companies made false representations about their products' addictiveness and effectiveness, all calculated to mislead the state, prescribers, and the public. This argument proved powerful in suits against tobacco companies.

A third strategy calls out companies' lax monitoring of suspicious opioid orders. The federal Controlled Substances Act requires drug suppliers to maintain effective controls against, and notify the Drug Enforcement Agency of, potentially illegitimate orders.

Whereas tobacco lawsuits benefited from leaked evidence that tobacco companies were aware of nicotine's addictiveness and sought to understate it and manipulate nicotine levels in tobacco products, no comparable whistleblower evidence has emerged with regard to opioids. Without such evidence, it is harder to establish an intent to deceive. Nevertheless, other information may help prove that companies knew that what they were doing was harmful: admissions of liability in some settlements; documents obtained in government investigations, investigative reporting, and litigation; and marketing practices that persisted despite mounting evidence linking opioids to adverse health outcomes.[2,4,5]

A final strategy highlights the profits that opioid companies have reaped at the government's expense through allegedly unfair business practices. In these "unjust enrichment" claims, governments argue that opioid companies should have to disgorge such profits. This argument has intuitive appeal, as it did in litigation over tobacco, firearms, and lead paint, because attorneys can point to huge pecuniary gains enjoyed while the government was saddled with vast medical and law-enforcement costs. Such claims have struggled to find legal footing in cases involving other products because courts typically require the government to show that it conferred a benefit on the company. For opioids, though, government payment for excessive prescriptions under public insurance programs directly contributed to companies' profits. Already, two large settlements have occurred in cases that included unjust enrichment claims, although pharmaceutical companies avoided admitting fault (see table).

Notwithstanding the $600 million federal settlement with Purdue in 2007 — one of the largest in history with a drug company — opioid litigation has yet to financially dent the $13-billion-a-year opioid industry. Moreover, opioid litigation victories have all taken the form of settlements, in which companies usually have not admitted any fault. Even where litigation costs have no prospect of exceeding the economic benefits of continuing to produce a dangerous product, though, litigation can have value as a public health strategy and may mitigate some harms of the opioid epidemic.

The funds obtained in several government suits have provided desperately needed resources for opioid addiction treatment and law enforcement. Future payouts, reasonably likely to increase in frequency and magnitude, could also be earmarked for other support services for persons with addiction — such as housing and employment assistance — and for distributing the overdose-reversal drug naloxone. Past experience suggests that the challenge will be ensuring that the windfalls to state governments are not diverted to unrelated purposes.

Litigation could also help alleviate the opioid epidemic by changing industry practices and building public awareness. Settlement agreements may include commitments to modify particular marketing and distribution practices, as in the case of McKesson (see table). Lawsuits may bring to light harmful, unethical, and even illegal business practices that sour

public opinion of opioid companies and prompt patients to ask more questions about what their doctor prescribes. Finally, snowballing litigation helps build the case for greater regulation. Win or lose, lawsuits that very publicly paint the opioid industry as contributing to the worst drug crisis in American history put wind in the sails of agencies and legislatures seeking stronger oversight.[5] Together, litigation and its spillover effects hold real hope for arresting the opioid epidemic.

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High-Profile Settlements against Opioid Companies, 2004–2017.*

Case	Key Dates	Allegations	Settlement Details
State and Local Government Suits			
West Virginia v. Purdue Pharma	Nov. 5, 2004 (settled)	• Aggressively marketing OxyContin to state residents, many of whom became addicted. • Concealing from prescribers the extent to which OxyContin's qualities could lead to addiction.	• $10 million paid over 4 yr to support drug abuse and education programs, law-enforcement initiatives, and medical programs on drug abuse. • No fault admitted.
26 states and District of Columbia v. Purdue Pharma	May 8, 2007 (settled)	• Unlawfully marketing OxyContin for off-label uses. • Misbranding OxyContin as "less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."	• $19.5 million • Purdue pledged not to promote OxyContin for off-label uses. • Requires Purdue to maintain abuse- and diversion-detection program, report problem prescribing, and have field sales personnel undergo special training before selling OxyContin • No fault admitted.
Kentucky v. Purdue Pharma	Oct. 4, 2007 (filed) Dec. 23, 2015 (settled)	• Committing Medicaid fraud by misrepresenting the risks and benefits of OxyContin, thereby costing Kentucky Medicaid millions in drug and treatment costs. • Engaging in false advertising by means of false and misleading package inserts, promotion, and marketing. • Reaping unjust enrichment by profiting from OxyContin while state paid associated medical and drug costs.	• $24 million paid over 8 yr, to be spent on addiction treatment. • No fault admitted. • Judge granted media request to unseal the court documents to make Purdue practices known to the public.
West Virginia v. Cardinal Health	June 26, 2012 (filed) Jan. 9, 2017 (settled)	• Violating West Virginia Controlled Substances Act by failing to diligently respond to suspicious orders. • Engaging in unfair and deceptive practices, in violation of the West Virginia Consumer Credit and Protection Act. • Creating a public nuisance because diversion of drugs led to increased crime and consumption of law-enforcement and health care resources. • Reaping unjust enrichment while state expended substantial resources on prescription opioid epidemic.	• $20 million paid by Cardinal Health (distributor). • $16 million paid by AmerisourceBergen (distributor). • $2.4 million paid by Miami-Luken (distributor). • No fault admitted.
California v. Purdue Pharma	May 21, 2014 (filed) May 24, 2017 (settled with Teva)	• Engaging in false advertising by deceptively marketing opioid drugs meant for short-term use as appropriate for chronic pain. • Engaging in unfair competition, in violation of the California Unfair Competition Law. • Creating a public nuisance under California law, by engaging in deceptive marketing that led to an epidemic of opioid abuse.	• $1.6 million paid by Teva Pharmaceuticals, to be spent on combatting the ongoing opioid epidemic impacts in Santa Clara and Orange Counties. • Bars Teva from deceptive marketing. • No fault admitted by Teva. • Charges against Purdue, Endo Health Solutions, Janssen, and Actavis remain unresolved, although litigation was stayed by state court judge pending the outcome of FDA studies related to the risks of long-term opioid treatment.
Federal Government Suits			
U.S. v. Purdue Frederick	May 10, 2007 (filed) June 25, 2007 (settled)	• Violating the FDCA by misbranding OxyContin with the intent to defraud or mislead.	• $600 million paid by Purdue. • $34 million paid by 3 of Purdue's top executives. • Parties admitted they misled physicians and patients about the product's addictiveness and misbranded it as abuse resistant.
U.S. v. Cardinal Healthcare	Dec. 23, 2016 (settled)	• Violating the CSA by failing to report suspicious orders of controlled substances to pharmacies in Maryland, Florida, and New York. • Violating Washington record-keeping laws.	• $44 million • Cardinal admitted failure to report suspicious orders to the DEA.

Case	Key Dates	Allegations	Settlement Details
U.S. v. McKesson Corporation	Jan. 5, 2017 (settled)	• Violating the CSA by failing to maintain effective controls against diversion of controlled substances, including opioids, and to report suspicious orders to the DEA. • Violating a 2008 administrative agreement with the federal government to monitor sales and report suspicious orders to the DEA.	• $150 million • Requires McKesson to suspend sales of controlled substances from distribution centers in Colorado, Ohio, Michigan, and Florida for 3, 2, 2, and 1 years, respectively. • Because McKesson admitted failure to report suspicious pharmacy orders, it agreed to enhanced compliance with earlier 2008 agreement (which had also included a $13.25 million settlement).
U.S. v. Mallinckrodt	July 11, 2017 (settled)	• Violating the CSA by failing to notify DEA of suspicious orders, as well as to implement an effective system to detect such orders.	• $35 million • Allows DEA to analyze data Mallinckrodt collects on orders from customers. • No fault admitted.
Foreign Suits			
Canada v. Purdue Pharma (class action)	June 8, 2007 (commenced) Aug. 24, 2017 (settlement approved)	• Failing to disclose the known risk of addiction and withdrawal associated with OxyContin and OxyNEO to a class of persons who were prescribed and ingested these products from Jan. 1, 1996 through Feb. 28, 2017.	• $20 million (Canadian) settlement proposed and accepted by 3 of 4 jurisdictions overseeing the cases, consisting of: ○ $2 million to provincial health providers, ○ $4.5 million in legal fees, and ○ ~$13,000–$17,000/class member (varies on the basis of many factors).

*CSA denotes Controlled Substances Act; DEA, Drug Enforcement Agency; FDCA, Food Drug and Cosmetic Act; and FDA, Food and Drug Administration.